K033298

DEC 12 2003

510(k) SUMMARY

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Submitted by:	Masimo Corporation 2852 Kelvin Ave Irvine, CA 92614-5826 (714) 250-9688 FAX (714) 250-9686
Company Contact:	James J. Cronin, Vice President, Regulatory Affairs/Quality Assurance
Date Summary Prepared:	October 11, 2003
Trade Name	SPO2.COM Oximetry Sensors
Common Name	Oximeter Sensor
Classification Name and Product Code:	Oximeter (74DQA) (870.2700) Cable, Transducer and Electrode (74DSA) (870.2900)
Substantially Equivalent Devices:	Masimo SET® Radical Pulse Oximeter with SatShare™ and LNOP® series of Sensors and Cables 510(k) Number - K031330 Nellcor N-395 Pulse Oximeter – K991823 Nellcor N-200 Pulse Oximeter – K863784

Device Description

The SPO2.COM Oximetry Sensors are fully compatible disposable and reusable replacement sensors for use with Nellcor and Nellcor compatible pulse oximeter monitors. They represent a design change to the Masimo LNOP Oximetry Sensors.

The SPO2.COM RSI reusable sensor is essentially identical to Masimo LNOP-DCI sensor except for the connector at the end of the cable which interfaces with the Nellcor type patient cable. The emitter and detector are mounted in opposing halves of the molded clothespin style sensor with contoured pads to maintain contact with the patient's fingers. The same emitter (with Red wavelength of 658 nm and Infrared wavelength of 905 nm) and detector are used in both the SPO2.COM RSI and LNOP-DCI sensors. The patient contacting materials in the SPO2.COM RSI and LNOP-DCI sensors are the same. The SPO2.COM RSI sensors are supplied non-sterile.

The SPO2.COM disposable sensors are similar in construction to the predicate devices. The emitter and detector are connected to the cable assembly. The sensors have an adhesive bandage to allow the sensor to be attached to the patient's finger or toe. The same emitter (with Red wavelength of 658 nm and Infrared wavelength of 905 nm) is used in Masimo's LNOP series of disposable sensors. Four sizes of disposable SPO2.COM sensors are available for use with adult, pediatric, infant and neonatal patients. The four sensors are essentially identical except for the emitter and detector spacing and size and orientation of the bandage material. The patient contacting materials in the SPO2.COM disposable sensors are the same that is used in Masimo's LNOP sensor line. The SPO2.COM disposable sensors are supplied non-sterile for single patient use.

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The SPO2.COM patient cables are similar in construction to the predicate device enabling the SPO2.COM Oximetry Sensors to be connected to Nellcor and Nellcor compatible pulse oximeter monitors.

Predicate Devices

SPO2.COM Sensor Line	Masimo Predicate LNOP Sensors – in K031330	Nellcor Predicate Sensors found in K863784 and K991823
SPO2.COM RSI – Reusable Adult Sensor	LNOP-DCI	DS-100A
SPO2.COM A – Adult Disposable Sensor	LNOP-Adt	D-25
SPO2.COM P – Pediatric DisposableSensor	LNOP- Pdt	D-20
SPO2.COM I – Infant Disposable Sensor	LNOP-Neo	I-25
SPO2.COM N – Neonatal Disposable Sensor	LNOP-Neo	N-25
SPO2.COM 200 - Patient Cable	PC Patient Cable	N/A
SPO2.COM 395 – Patient Cable	PC Patient Cable	N/A

Intended Use

The SPO2.COM oximetry sensors and cables are intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) for adult, pediatric, infant, and neonatal patients in hospitals, hospital-type facilities, mobile, and home environments.

Technology Comparison

The SPO2.COM oximetry sensors are substantially equivalent in intended use, design, principles of operation, materials, and performance to predicate sensors and operate on identical principles of non-invasive optical assessment of tissue oxygenation using emitters and detectors.

The SPO2.COM oximetry sensors are designed, configured, and manufactured for full compatibility with Nellcor and Nellcor compatible pulse oximeters. The SPO2.COM oximetry sensors are constructed of similar materials and components of equivalent specifications as used in the predicate devices.

The accuracy of the SPO2.COM oximetry sensors is equivalent to those of the predicate devices.

Performance Testing

Biocompatibility

All the patient contacting materials used in the SPO2.COM sensors are the same materials that are used in Masimo's LNOP series of sensors. Test results demonstrated that the materials were non-toxic, non-irritating, and non sensitizing.

Environmental Testing

Applicable environmetal testing per the Reviewers Guidance for Premarket Submissions - November 1993, i.e. electrical, mechanical and environmental were performed and all tests passed

Clinical Testing

Clinical studies were performed using the SPO2.COM Adult and Reusable oximetry sensors on healthy adult volunteer subjects during no motion conditions who were subjected to a progressive induced hypoxia and measuring the arterial hemoglobin saturation value with the instruments against the arterial hemoglobin oxygen determined from arterial blood samples with a CO-Oximeter. Clinical testing of the SPO2.COM Adult and Reusable sensors resulted in an accuracy of less than 2% SpO_2 A_{RMS} in the range of 70%-100% SaO_2 for adults, pediatrics and infants and less than 3% A_{RMS} for neonates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2003

Mr. James J. Cronin
Vice President, Regulatory Affairs/Quality Assurance
Masimo Corporation
2852 Kelvin Avenue
Irvine, California 92614-5826

Re: K033298
Trade/Device Name: SPO2.COM A, P, I, N, RS-I Pulse Oximeter Sensors
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: December 5, 2003
Received: December 8, 2003

Dear Mr. Cronin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033298

Device Name: SPO2.COM Sensors and Cables

Indications For Use:

The SPO2.COM Sensors and Cables are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) for use with adult, pediatric, infant, and neonatal patients in hospitals, hospital-type facilities, mobile, and home environments.

Prescription Use ___X_____ **AND/OR** **Over-The-Counter Use** _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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